

10/575615

AP20 Rec'd PCT/PTO 12 APR 2006

APPENDIX C

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/004416

International filing date (day/month/year)
19.10.2004

Priority date (day/month/year)
17.10.2003

International Patent Classification (IPC) or both national classification and IPC
A61M15/00

Applicant
VECTURA LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for International preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

10/575615

International application No.
PCT/GB2004/004416

IAP20 Rec'd PCT/PTO 12 APR 2006

Box No. 1 Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/004416

Box No. II Priority

1. ☒ The following document has not been furnished:

- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. ☐ It has not been possible to consider the validity of the priority claim because a copy of the priority document was not available to the ISA at the time that the search was conducted (Rule 17.1). This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.
4. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/004416

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 32-35

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the whole application or for said claims Nos. 32-35

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☒ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/004416

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☒ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☐ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☒ all parts.
 - ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	2-13,16-20,23,25-31, 36-63
	No: Claims	1,14,15,21,22,24,64-70
Inventive step (IS)	Yes: Claims	36-63
	No: Claims	1-31,64-70
Industrial applicability (IA)	Yes: Claims	1-31,36-70
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/GB2004/004416

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2004/004416

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Rule 67(iv) PCT: Claims 32-35 relate to a method for treatment of the human or animal body by therapy: a method of using an inhaler. The method includes inhaling through the mouthpiece to entrain a dose of medicament and carry it to the user's airway.

Re Item IV

Lack of unity of invention

This International Preliminary Examination Authority considers that there are the following 2 inventions claimed in the international application:

- a) the subject-matter of independent claim 1, followed by dependent claims 2 to 31 and 64-70,
- b) the subject matter of independent claim 36, followed by dependent claims 37 to 63.

These 2 inventions are not so linked that they form a single general inventive concept (Rule 13.2 PCT). The single general inventive concept linking the inventions according to different claims can be defined by the common features of these claims. In the present case these common features are at the most an inhaler, comprising a housing to receive a plurality of blisters each having a puncturable lid and containing a dose of medicament for inhalation by a user, and a blister piercing means (a member in claim 1 and a head in claim 36) for puncturing the lid of a blister so that the dose contained in the blister can be subsequently inhaled by the user.

An inhaler according to these features, however, is known from the document WO01/26720 (see for example figures 11-14).

Consequently, the single general concept in the present case is not novel (and hence non inventive) and the application, therefore, does not comply with the requirements of unity of invention (Rule 13.1 PCT).

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following documents :

D1: GB-A-2 340 758 (BESPAK PLC) 1 March 2000 (2000-03-01)

D2: WO 99/47099 A (SCHUCKMANN ALFRED VON ; HETZER ULRICH (DE); KUBLIK
HEIKE (DE); HECKENM) 23 September 1999 (1999-09-23)

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

Document D1 discloses an inhaler (1) comprising a housing (4) to receive a plurality of blisters (11) each having a puncturable lid (22) and containing a dose of medicament (21) for inhalation by a user, a mouthpiece (2) through which a dose of medicament is inhaled by a user, and an actuator (2, 50, 51, 52) operable to sequentially move each blister into alignment with a blister piercing member (30), said actuator being operable to cause the blister piercing member to puncture the lid of an aligned blister such, that, when a user inhales through the mouthpiece, an airflow through the blister is generated to entrain the dose contained therein and carry it out of the blister and via the mouthpiece into the user's airway (page 11, lines 2-16).

2. Dependent claims 2-31 and 64-70 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (claims 1,14,15,21,22,24,64-70) or inventive step (claims 2-13,16-20,23,25-31), see documents D1 and D2 and the corresponding passages cited in the search report.

It is to be mentioned, that:

- a pivotally mounted cocking means (actuator of claims 2-4), pivotally attached cap (claims 18-20),
- a blister pack according to the features of claims 25-27, and
- an inhalator consisting of limited number of translucent components (claims 28-

31)

represent an obvious selection for a skilled person.

3. The subject-matter of independent claim 36 appears to be new (Article 33(2) PCT) and inventive (Article 33(3) PCT).

Document D2 is regarded as being the closest prior art to the subject-matter of claim 36, and shows an inhaler comprising a housing to receive one or more blisters (11, 12) having a puncturable lid (26, 27) and containing a dose of medicament (21, 22) for inhalation by a user, the device comprising a blister piercing head (64) for puncturing the lid of a blister so that the dose contained therein can be inhaled by the user from the blister through the device, wherein the piercing head comprises a primary cutting element (127) which is configured to cut, as the piercing member enters the blister, a first linear slit in the lid and, secondary cutting elements (129, 131), which are configured to cut second linear slits, as the piercing head continues to enter the blister (fig. 12(a)-14(b)).

The subject-matter of claim 36 differs from this known inhaler in that the secondary cutting elements extend laterally from the primary cutting element and the second linear slits extend across each end of the first linear slit, and the primary and secondary cutting elements form together a pair of flaps in the lid which are folded aside by the piercing head upon further entry of the piercing head into the blister.

The problem to be solved by the present invention may be regarded as how to improve the efficiency of emptying a blister during application (inhalation) on a simple way (with a simple construction of the puncturing head).

All documents cited in the search report do not mention or even suggest such construction of the head.

Claims 37-63 are dependent on claim 36 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII

Certain defects in the International application

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2004/004416

1. Independent claims 1 and 36 is not drafted in the two-part form, as normally required by Rule 6.3(b) PCT.
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. All dependent claims referring back to several previous claims shall be grouped together to the extent and in the most practical way possible (Rule 6.4(c) PCT), which is not the case for claims 64-70.